initially filed with claims 1-80, claims 81-105 were added, and claims 37-91 were cancelled, leaving claims 1-36, and 92-105 pending in that application at the time the present continuation-in-part application was filed claiming that application as a parent application. Therefore, in accordance with MPEP 608.01(j), the original numbering of the claims at the initial filing of the present application was as follows: claims 1-36 and 92-105 pending; and claims 37-91 cancelled.

In their preliminary amendment, the Applicants cancelled claims 2, 94, and 103-105 and added claims 106-113, consistent with the numbering of the claims of the parent application throughout the application, leading to the statement above in the Remarks section that claims 1, 3-36, 92-93, and 95-102 remain pending in this application and claims 106-113 are added to the application. Apparently the Examiner believes that the present application either reverted back to the original claims 1-80 of the parent application U.S. Ser. No. 08/996,976, or was filed as an original, non-continuing application. However, neither of these options is possible. The first option is not possible under MPEP 608.01(j), since claims 37-80 were canceled in the parent application, and would have to be renumbered as claims 106-149 under MPEP 608.01(j) if the Applicants' intent was to pursue the originally cancelled claims 37-80 in the continuation-in-part application. The second option is not possible since the Applicants clearly indicated in the papers filed with the present application that the present application claimed priority from the parent application U.S. Ser. No. 08/996,976 and was filed as a continuation-in-part application. In short, the present application is a continuation-in-part application of U.S. Ser. No. 08/996,976 and must maintain the numbering of the parent application as numbered throughout the prosecution of the parent application to comply with MPEP 608.01(j). The Applicants' Preliminary Amendment was filed consistent with the claim numbering of the parent application throughout the parent application, and the Examiner's interpretation of the claim numbering is not consistent with MPEP 608.01(j). As such, Applicants request the entry of the claims in accordance with the preliminary amendment filed with the original filing papers of the present application.

In the Office Action of February 7, 2003 Applicants were requested to update the status of the parent file at page 1, line 1 of the present application. Applicants have done so.

In the Office Action of February 7, 2003 claims 1 and 3-36 were rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-36 of co-pending Application No. 09/912,494. Applicants have filed a provisional terminal disclaimer of co-pending Application No. 09/912,494 with this response to overcome this rejection.

In the Office Action of February 7, 2003 claims 1 and 3-36 were rejected under 35 USC §102(b) as anticipated by EP 0 380 343. Applicants respectfully traverse the rejection.

Claim 1 and its dependent claims 3-36 provide methods for producing a soy protein material in which an aqueous slurry of a soy protein material is treated with an enzyme preparation containing an acid phosphatase enzyme to degrade ribonucleic acids in the soy protein material, and then the soy protein material is washed to remove degraded ribonucleic acids.

EP 0 380 343 A2 (the "'343 patent) teaches a method for production of phytate-free or low-phytate soy protein isolates or soy protein concentrates. The '343 patent is directed to a method of degrading phytates with one or more phytate-degrading enzymes, where acid phosphatases are disclosed as one type of phytate-degrading enzyme. The '343 patent does not disclose or mention ribonucleic acids at all.

Claim 1 and its dependent claims are not explicitly anticipated by the '343 patent since the '343 patent does not disclose ribonucleic acids at all, and clearly does not teach any means of degrading ribonucleic acids or washing a soy protein material to remove degraded ribonucleic acids. Therefore, the only possible basis for anticipation is that the claims are inherently anticipated by the '343 patent.

Claim 1 and its dependent claims, however, are not inherently anticipated by the '343 patent since the process disclosed by the '343 patent does not necessarily result in the degradation of ribonucleic acids in a soy protein material by an enzyme preparation containing an acid phosphatase. Anticipation by inherency applies when a claimed element is "always present" and "naturally flows" from the prior art disclosure.

Inherency may not be established by probabilities or possibilites—the mere fact that a certain thing may result from a given set of circumstances is not sufficient. See *In re Oelrich*, 212 USPQ 323, 326 (CCPA 1981). More particularly, for a claim element to be anticipated inherently by a reference the element must be a necessary consequence of what was deliberately intended as disclosed in the prior art reference. *Mehl/Biophile International Corp. v. Milgraum*, 52 USPQ2d 1303, 1307 (CAFC 1999). Occasional results are not inherent. *Id.* at 1306. See also *Trintec Industries Inc. v. Top-U.S.A. Corp.*, 63 USPQ2d 1597, 1599 (CAFC 2002); *In Re Robertson*, 49 USPQ2d 1949, 1950-51 (CAFC 1999); *Rosco Inc. v. Mirror Lite Co.*, 64 USPQ2d 1676, 1679-81 (CAFC 2002); and *Continental Can Co. USA v. Monsanto Co.*, 20 USPQ2d 1746, 1748-1750 (CAFC 1991).

The Office Action clearly shows that the basis for the §102(b) rejection is that the EP 0 380 343 reference teaches a process that produces the presently claimed processes wherein ribonucleic acids in a soy protein material are reduced by degrading the ribonucleic acids with an enzyme preparation containing an acid phosphatase enzyme because the reference utilizes a FINASE® enzyme preparation that contains an acid phosphatase to degrade phytates in an aqueous slurry of soy protein material. Applicants note, however, that the reference teaches a process that may utilize an enzyme preparation that contains an acid phosphatase enzyme in a soy protein material, but does not teach that the enzyme preparation must contain an acid phosphatase enzyme—and, therefore, the claims of the present application are not inherently anticipated by the cited reference.

The reference does not limit the enzyme preparations used to reduce phytates in soy protein to FINASE® enzyme preparations. Specifically, on page 6, lines 38-41 the EP 0 380 343 A2 reference states:

> Stated most simply, in its broadest terms the present invention comprises:
> (a) suspending defatted soy bean particulate in an aqueous medium in the presence of an enzyme preparation comprising one or more phytate-degrading enzymes (emphasis added): and
> (b) isolating the resulting phytate-free or low phytate soy protein.

The reference explains what phytate-degrading enzymes are, with respect to the invention of the reference (page 6, lines 16-27):

> In the various aspects of the present invention, phytic acid is eliminated by means of effective commercially available bulk enzyme compositions. Phytate-degrading enzymes dephosphorylate inositol-hexaphosphate to yield inositol and orthophosphate, several forms of inositolphosphates being the intermediate products. Phytate degrading enzymes include phytase and acid phosphatases.
>
> Phytase and acid phosphatases are produced by various microorganisms such as Aspergillus spp., Rhizopus spp., and yeasts (Appl. Microbiol. 16: 1348-1357 (1968 Enzyme Microb. Technol. 5: 377-382 (1983)), and phytase is also produced by various plant seeds, for example wheat, during germination. According to methods known in the art, enzyme preparations can be obtained from the above mentioned organisms. Caransa et al. Netherlands Pat. Appl. 87.02735, found that at the same enzyme dosage phytase from Aspergillus spp. degraded phytic acid in corn more efficiently than phytase from wheat.
>
> Particularly preferred for the purposes of the present invention are the Finase enzymes, formerly termed Econase EP 43 enzymes (emphasis added), manufactured by Alko Ltd., Rajamaki, Finland.

Thus, the reference discloses that use of the FINASE® enzyme preparations is a preferred method of practicing the disclosed invention, but that the process of the reference is not limited to use of FINASE® enzymes and can utilize any phytate-degrading enzyme preparation containing one or more phytate-degrading enzymes, where such enzyme preparations can be produced from *Aspergillus spp.*, *Rhizopus spp.*, yeasts, and various plant seeds such as wheat.

These enzyme preparations do not necessarily contain an acid phosphatase enzyme effective to degrade ribonucleic acids in a vegetable protein material. The reference itself implies that enzyme preparations useful in the process of the reference that contain phytase, but not acid phosphatase, can be derived from various plant seeds, for example wheat, during germination. The absence of acid phosphatase enzymes in these plant seed phytase enzyme preparations can be inferred from the sentence in which it is disclosed that phytase and acid phosphtases are produced by various microorganisms, yet the plant seed enzyme preparations are disclosed as only containing phytases (EP 0 380 343 A2 p. 6, lines 20-22). As such, it is clear that the reference discloses enzyme preparations containing no acid phosphatase enzymes among the enzyme preparations that are effective to practice the method of reducing phytates and phytic acid in accordance with the method of the reference.

Even enzyme preparations derived from microorganisms such as *Aspergillus spp.* do not necessarily contain an acid phosphatase enzyme effective to practice the claimed invention. There are numerous strains of phytase producing *Aspergillus spp.*, including *Aspergillus oryzae, Aspergillus niger, Aspergillus flavus, Aspergillus terrus, Aspergillus carneus,* and *Aspergillus fumigatus*, not all of which produce enzyme preparations

containing acid phosphatase that are effective to degrade ribonucleic acids in accordance with the present invention. For example, NAUTUPHOS® is an enzyme preparation that is commercially sold as a phytase (*see* Exhibit A attached hereto) that is derived from *Aspergillus niger*, yet does not degrade ribonucleic acid in a vegetable protein material in accordance with the current claims (*see* Exhibit B attached hereto). Such phytate-degrading enzyme preparations clearly fall within the description of the process of the reference since they degrade phytates and phytic acid when utilized in accordance with the disclosed process (*see* Exhibit B).

The cited reference, therefore, clearly did not intend to limit the disclosed method of reducing phytates and phytic acids to using only FINASE® enzyme preparations. Page 6, lines 16-27, of the EP 0 380 343 A2 reference certainly indicates that other phytase enzyme preparations were contemplated for use in the disclosed process, particularly since FINASE® is derived from *Aspergillus niger*, yet the reference discloses many other sources of phytase enzymes. Furthermore, claim 3 of the cited reference states that the method of the reference is intended to include enzymes originating from *Aspergillus spp., Rhizopus spp.,* and yeast. Therefore, the deliberate intent of the cited reference, to degrade phytates and phytic acid, can be achieved utilizing other enzyme preparations that do not degrade ribonucleic acids or do not contain an acid phosphtase enzyme (e.g. NATUPHOS® enzyme).

The Examiner may have reached this conclusion as well, since page 6 lines 7-9 of the Office Action of February 7, 2003 states "Further, in view of the teaching of FINASE in the cited EP reference it is apparent that the preparation may indeed include an acid phosphatase". Under the case law cited above, the fact that the process of the cited EP reference may indeed contain an acid phosphatase is insufficient to establish inherent anticipation. The process of the cited reference must always contain an acid phosphatase in order to establish inherent anticipation.

Furthermore, even if the FINASE enzyme preparation disclosed in the '343 patent as a preferred enzyme preparation always degrades ribonucleic acids in the slurry of soy protein material, the '343 patent disclosure of the use of the FINASE enzyme preparation in a soy material is insufficient to establish inherent anticipation because the deliberate intent of the '343 patent is to degrade phytates with one or more phytate-degrading

enzymes, which can be accomplished, as discussed above, with other non-FINASE enzymes that do not result in the degradation of ribonucleic acids. It is irrelevant to a determination of anticipation by inherency if a FINASE enzyme preparation always degrades ribonucleic acids in an aqueous slurry of a soy protein material in the process taught in the '343 patent because the deliberate intent of the '343 reference is to degrade phytates in a soy protein material with one or more phytate degrading enzymes that are not limited to FINASE enzyme preparations. As the Mehl/Biophile case requires, inherent anticipation is determined in accordance with the deliberate intent of the cited reference, and clearly the cited reference deliberately intended to include enzyme preparations beyond FINASE enzyme preparations as useful for degrading phytates in a soy protein material. Therefore, degradation of ribonucleic acids is not a necessary consequence of the deliberate intent of the process of the '343 patent, and the disclosure of the '343 patent does not inherently anticipate the present invention.

In the Office Action of February 7, 2003, claims 1 and 3-36 were rejected under 35 U.S.C. §103(a) as obvious over EP 0 380 343. Applicants respectfully traverse the rejection.

Claim 1 and its dependent claims 3-36 were rejected as obvious over the '343 patent since allegedly any difference between the claims and the '343 patent is considered to be so slight as to render the claims *prima facie* obvious over the '343 patent. As noted above, however, the '343 patent provides no disclosure at all relating to degrading ribonucleic acids. One skilled in the art would learn absolutely nothing about how to degrade ribonucleic acids from the '343 patent, and thus one skilled in the art would never look to the '343 patent for any guidance in determining an effective method for degrading ribonucleic acids in a soy protein material. Therefore, no basis whatsoever has been established for a case of *prima facie* obviousness based on the disclosure of the '343 patent.

In light of all of the above, entry of the claims of the preliminary amendment and allowance of claims 1 and 3-36 are requested.

Respectfully submitted,
WONG ET AL

Date: July 1, 2003

By: _____
Richard Taylor Reg. No. 37,248
Lead Patent Counsel
Solae, LLC
(314) 982-3004

EXHIBIT A

BASF Aktiengesellschaft BASF

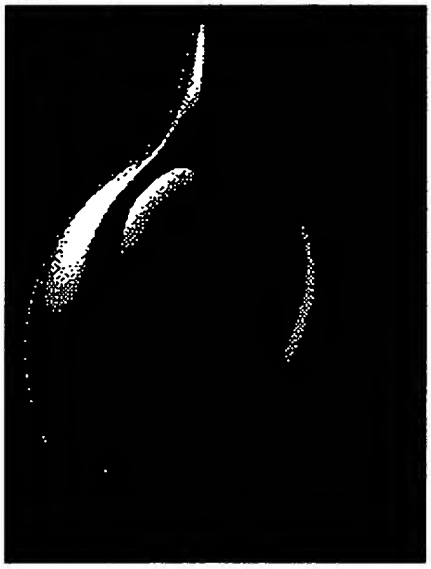
The natural key to higher yields

natuphos®

Our current product portfolio comprises:

- Natuphos®
- Natugrain®
- Natuphos Combi®
- Natustarch®
- Screensaver
- BASF Aktiengesellschaft
- DSM

The original phytase



Natuphos® offers the following benefits:

- Improvement of phosphorus digestibility in pig and poultry diets
- Quantified improvement of nutrient digestibility and energetic value of feed
- Saving of feed costs due to reduction of expensive feed ingredients in the feed formula
- Reduced excretion of phosphorus (over 30 % less)
- Outstanding bioefficacy

Natuphos® is available in a wide range of product formulations, providing powder, granule or liquid products of different phytase concentrations:
Natuphos® 5000
Natuphos® 5000 G
Natuphos® 5000 L
Natuphos® 10000 G*
Natuphos® 10000 L*

The original phytase
The development of Natuphos® was prompted by environmental problems in regions with high livestock density. Its microbial 3-phytase, obtained from *Aspergillus niger*, releases phosphorus from phytate, the storage form of phosphorus in vegetable feed compounds, which is more or less undigestible to pigs and poultry.
Thus, supplementation of feed with Natuphos® markedly increases the availability of phosphorus but also of other phytate-bound minerals and nutrients. Released from phytate, these nutrients can be efficiently used by the animal instead of being lost with the manure.

Reliable efficiency
The use of Natuphos® ensures a maximum release of digestible phosphorus from vegetable feedstuffs per phytase unit. Numerous feeding trials have shown the superior bioefficacy of Natuphos® compared to competitor products based on *Peniophora lycii* phytase. The mean exchange rate of Natuphos® versus Peniophora phytase in liquid products amounts to 1:1.5, in granular products it is at least 1:2.

L ss phosphorus in the manure
Since Natuphos® improves phosphorus digestibility, feed supplementation with inorganic phosphorus can be reduced. In this way, Natuphos® decreases the excretion of phosphorus by over 30 %, providing ecological and economical benefits.

F ed optimisation with Natuphos®
Based on the results of numerous feeding trials, nutrient equivalencies have been

developed for Natuphos®. These figures express the extent to which nutrients are released by Natuphos® from phytate in the feed. They can be used in the same way as analysed nutrient contents of feed compounds to optimise least cost formulas. Feed optimisations reveal the economic advantages which can be gained by supplementing rations with Natuphos®.

Natuphos® formulations
Different formulations and concentrations of Natuphos® help to meet the customers' individual requirements for the manufacturing of quality feed under different production conditions:

POWDER
Natuphos® 5000:
fine, yellowish brown powder, recommended for use in non-pelleted compound feed and feed pelleted below 75°C
min. 5.000 FTU/g phytase activity

GRANULES
Natuphos® 5000 G:
fine white granules, recommended for use in compound feed pelleted up to 85°C
min. 5.000 FTU/g phytase activity
Natuphos® 10000 G*:
highly concentrated, fine white granules, recommended for use in concentrated premixes and in compound feed pelleted up to 85°C
min. 10.000 FTU/g phytase activity

LIQUIDS
Natuphos® 5000 L:
yellowish brown liquid, recommended for use in compound feed pelleted above 85°C (post pelleting application)
min. 5.000 FTU/g phytase activity
Natuphos® 10000 L*:
highly concentrated, yellowish brown liquid, recommended for use in compound feed pelleted above 85°C (post pelleting application)
min. 10.000 FTU/g phytase activity

*Available only outside the European Union

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EXHIBIT B

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner	: Deborah K. Ware
Group Art Unit:	: 1651
Applicants	: Wong et al.
Serial No.	: 09/912,471
Filed	: July 24, 2001
For	: METHOD FOR PRODUCING ULTRAPURE PROTEIN MATERIALS

Hon. Commissioner of Patents and Trademarks
Alexandria, VA 22313-1450

Dear Sir:

DECLARATION UNDER 37 CFR §1.132

Theodore M. Wong declares as follows:

1. I am an inventor of the subject matter of the above identified patent application.

2. I received a Bachelor of Arts Degree in Biology from Greensboro College in May, 1974, a Masters Degree in Microbiology from the University of Texas at Arlington in May 1976 and a Ph.D. Degree in Food Science/Food Biochemistry from Louisiana State University in May, 1982.

3. I have been employed by Solae, LLC, previously known as Protein Technologies International, Inc., since August 19, 1985, and currently hold the position of Senior Research Director, Product Development R&D.

4. Under my direction and control an experiment was conducted to determine the extent of degradation of phospho- and diphospho-ester nucleoside containing compounds in a soy protein material by an acid phosphatase enzyme preparation in comparison with NATUPHOS® phytase enzyme. Three samples of soy protein curd at pH 4.6 were prepared. The first sample was used as a control sample ("Control"), the second sample was dosed with an acid phosphatase enzyme preparation having an enzyme activity of 1400 KPU per Kg curd solids ("Acid Phosphatase") and the third sample was dosed with NATUPHOS® phytase

enzyme preparation having an enzyme activity of 1800 FTU per Kg curd solids ("Natuphos"). After dosing the second and third samples with their respective enzyme preparations, the three samples were heated to 50°C for two hours. A sample of each of the three samples was then treated with bacterial alkaline phosphatase to degrade monomeric nucleotides to monomeric nucleosides and then the free monomeric nucleoside content of the treated samples was measured. The resulting free monomeric nucleoside content provides a measure of the amount of monomeric nucleotides and monomeric nucleosides present in the sample ("Monomerics"). Another sample of each of the three samples was treated with a nuclease to hydrolyze polymeric ribonucleic acids to monomeric nucleotides, then was treated with pyrophosphatase to hydrolyze ribonucleoside containing adducts to monomeric nucleotides, then was treated with bacterial alkaline phospatase to hydrolyze the monomeric nucleotides to free monomeric nucleosides, and then the free monomeric nucleoside content of the treated samples was measured. The resulting free monomeric nucleoside content provides a measure of the total amount of ribonucleoside containing compounds, both polymeric and monomeric, since the nuclease and pyrophosphatase treatments degrade the polymeric ribonucleoside-containing compounds to monomeric nucleotides, which are subsequently degraded to monomeric nucleosides with bacterial alkaline phosphatase ("Total"). The resulting ribonucleoside content by weight of nucleosides for each sample is shown in Table 1.

TABLE 1

Sample	Uridine	Cytidine	Guanosine	Adenosine	Total
Control					
--Monomerics	172	121	237	127	657
--Total	4302	5320	6711	5886	22219
Acid Phosphatase					
--Monomerics	5188	6886	7175	2204	21453
--Total	5281	7015	7599	2495	22390
Natuphos					
--Monomerics	231	128	240	184	783
--Total	4542	5628	6866	6070	23106

Table 1 shows that treatment with the acid phosphatase enzyme preparation produced a soy material product in which 95.8% [(21453/22390)*100] of all ribonucleoside containing compounds were either in their monomeric nucleoside form or their monomeric nucleotide form—clearly indicating the degradation of most polymeric ribonucleic acids in the soy material. Table 1 also shows that treatment with the NATUPHOS® phytase enzyme produced a soy material product in which 3.3% [(783/23106)*100] of all ribonucleoside containing products were either in their monomeric nucleoside form or their monomeric nucleotide form. The NATUPHOS® phytase enzyme degraded little or no polymeric ribonucleic acids, as can be shown by comparing amount of monomeric nucleosides and monomeric nucleotides in the soy material treated with NATUPHOS® to the Control, which contained 3.0% [(657/22219)*100] of all ribonucleoside containing products as monomeric nucleosides or monomeric nucleotides. NATUPHOS®, therefore, clearly did not degrade substantial amounts of ribonucleic acids to monomeric nucleosides or monomeric nucleotides, while the acid phosphatase enzyme preparation degraded almost all polymeric ribonucleoside-containing compounds to monomeric nucleosides and monomeric nucleotides.

5. Under my direction and control an experiment was conducted to determine the extent of degradation of phytic acid in a soy protein material by an acid phosphatase enzyme preparation in comparison with NATUPHOS® phytase enzyme. Three samples of soy protein curd at pH 4.6 were prepared. The first sample was used as a control sample ("Control"), the second sample was dosed with an acid phosphatase enzyme preparation having an enzyme activity of 1400 KPU per Kg curd solid ("Acid Phosphatase") and the third sample was dosed with NATUPHOS® phytase enzyme preparation having an enzyme activity of 1800 FTU per Kg curd solids ("Natuphos"). After dosing the second and third samples with their respective enzyme preparations, the three samples were heated to 50°C for two hours. A sample of each of the three samples was then analyzed to

determine phytic acid content, by weight percent of the soy protein material. The results are shown in Table 2.

TABLE 2

Sample	Phytic Acid (wt. %)
Control	1.46
Acid Phosphatase	0.12
Natuphos	0.11

Table 2 shows that both NATUPHOS® and the acid phosphatase enzyme preparation were effective to degrade phytic acid in a soy protein material relative to a soy protein material not treated with either enzyme. Tables 1 and 2, together, show that NATUPHOS® is effective to degrade phytic acid but not polymeric ribonucleoside-containing compounds such as ribonucleic acid, while an acid phosphatase enzyme preparation is effective to degrade both phytic acid and polymeric ribonucleoside-containing compounds such as ribonucleic acid.

Theodore M. Wong

Date: July 1, 2003